DiaSorin S.p.A.
Via Crescentino, snc
13040 Saluggia (VC) Italy
tel. +39 / 0161.487093
fax +39 / 0161.487628
www.diasorin.com

The Diagnostic Specialist

Urgent Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected products: LIAISON® Analyzer

FSCA-identifier (e.g. date): August 3rd, 2010

Date: August 3rd, 2010

Attention: Carefully read the information given in this Field Safety Notice.

Details on affected device:
Type of device: In Vitro Diagnostic Medical Device
Model name LIAISON® *Catalog – 9450200* and LIAISON® LAS *Catalog – I0041*
Batch/serial number : All serial numbers
Expiry date: N.A.

Description of the problem:
An investigation performed on the LIAISON® Analyzers confirmed the following issue:

i. During the System Initialization and exactly when the pipettors are washing, if either patient sample or reagent area flap (door) are opened, the shaker rod may stop moving;
ii. This event will affect the suspension of magnetic particles leading to a string of low RLU values for calibrators, controls and patient samples;
iii. A sequence of false positive or negative results, or incorrect dose may be experienced depending on the assay scheme.

The frequency of occurrence is anticipated to be very rare due to the limited time span (few seconds) in which these actions could potentially occur simultaneously. The ability to detect the issue is also considered to be very high since magnetic particle rotation is very visible and clearly audible to the User. In addition, a series of low RLU values and a series of unexpected patient, controls and calibrators results should also be recognized by the User.

As a consequence of the above DiaSorin deems that there is no need to review previous results.

Advise on action to be taken by the user:
- Never open either the reagent or sample flap (door) during the System Initialization Procedure.
- Carefully read the Technical Note 284, including clarification on the LIAISON® Analyzer initialization procedure.
- Fill the confirmation form to be sent back to the manufacturer

DiaSorin S.p.A.
Via Crescentino, snc
13040 Saluggia (VC) Italy
tel. +39 / 0161.487093
fax +39 / 0161.487628
www.diasorin.com

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Contact reference person:

Name: Antonella Fassio

Organisation: DiaSorin S.p.A

Address: Via Crescentino s.n.c.
13040 Saluggia (VC) Italy

Contact details: E-mail: antonella.fassio@diasorin.it
Tel. +39.0161.487.849

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency

Signature _____
Antonella Fassio
Corporate Quality Assurance and Regulatory Affairs Director
DIASORIN S.p.A.

DiaSorin
The Diagnostic Specialist

DiaSorin S.p.A.
Via Crescentino, snc
13040 Saluggia (VC) Italy
tel. +39 / 0161.487093
fax +39 / 0161.487628
www.diasorin.com

This section has to be filled in by the customer and returned to DiaSorin S.p.A.

RETURN TO FAX No: +39.0161.487.940
ATTN: Ms. ROSY VIRZI, QUALITY ASSURANCE

RETURN BY MAIL TO: DiaSorin S.p.A.
ATTN: Ms. ROSY VIRZI, QUALITY ASSURANCE
Via Crescentino snc
13040 Saluggia (VC) - Italy

I, the undersigned, have received the above Filed Safety Notice. I confirm I have read and understood the provisions as stipulated by DiaSorin.

Name (in capital letters) .....

Position Held .....
Hospital/Establishment .....

Department .....

Address .....

.....

City .....

Postcode .....

Country .....

Contact Number (or email) .....

LIAISON S/N .....

Signature .....

Date .....

LIAISON® Instrument Initialization Procedure

Dear User,

The purpose of this document is to supply further information about the LIAISON® initialization procedure; in particular, it is highlighted the correct way to interact with the analyzer while it is initializing after having switched it on or after a routine aborting.

User Documentation References

- **User Manual:** Chapter 4.2.3 "Starting the system on at the beginning of the working week"
  Chapter 4.2.4 "Starting the system on after a period of three or more days of inactivity"

- **Quick Guide**: Chapter 4.1 "Switching on the system"

The current document represents a clarification on the information already contained in the LIAISON® User Manual and in the LIAISON® Quick Guide according to Software Version 2.28. The next manuals' revision will include the below mentioned details.

Instrument initialization

Here below it is resumed the correct procedure to achieve a correct instrument initialization.

Prior performing the instrument initialization, ensure that all covers are placed in the original positions and both the flaps (sample area and reagents bay) are closed.

During the whole initialization procedure, the user must not interact with any parts of the instrument itself (e.g., opening flaps, exchanging bottles, etc.). The instrument shall be left untouched until the sequence is finished.

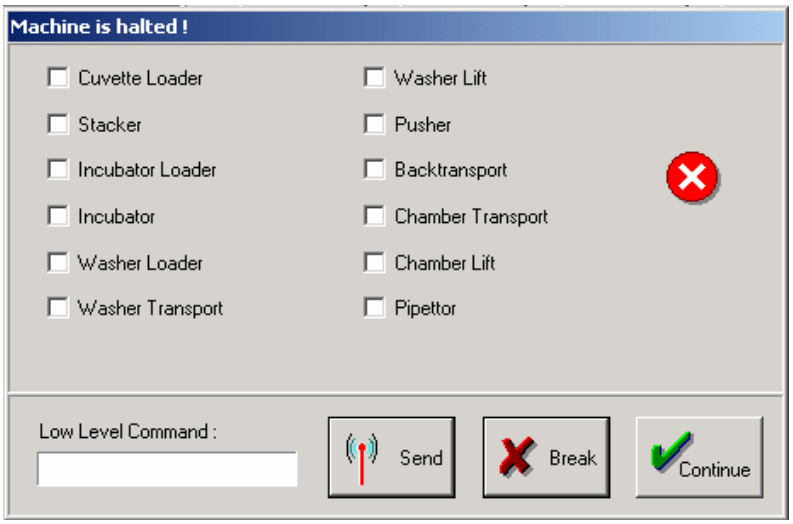
The initialization procedure can occur upon different situations:

- After having pressed the

button in the following pop-up:

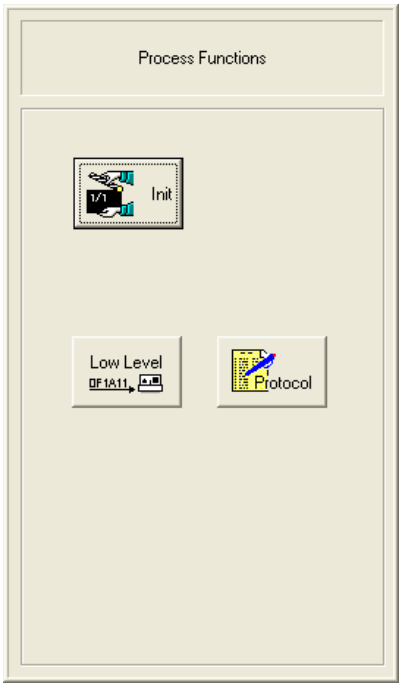
- After having pressed the

button in the following window:

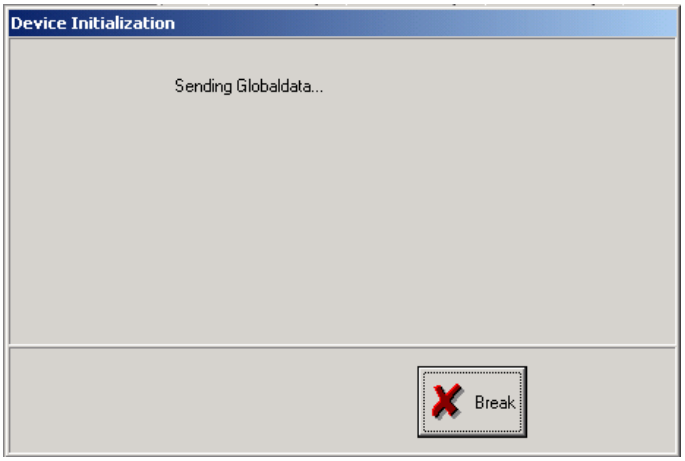


- After having pressed the

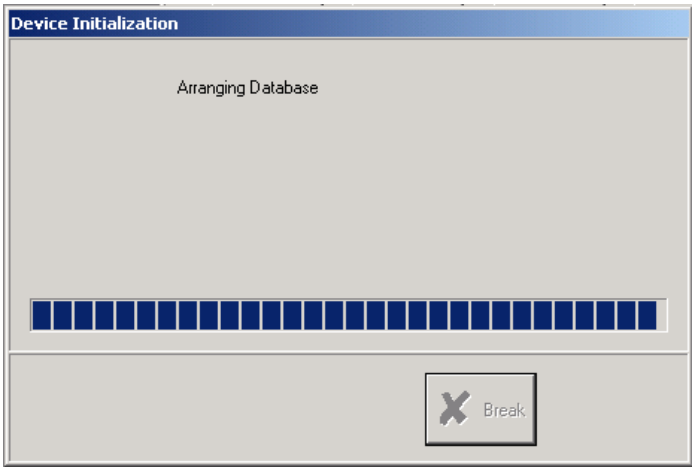
button:

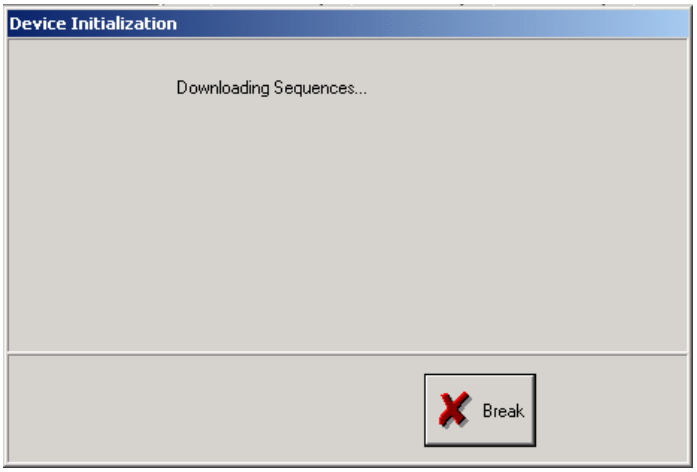


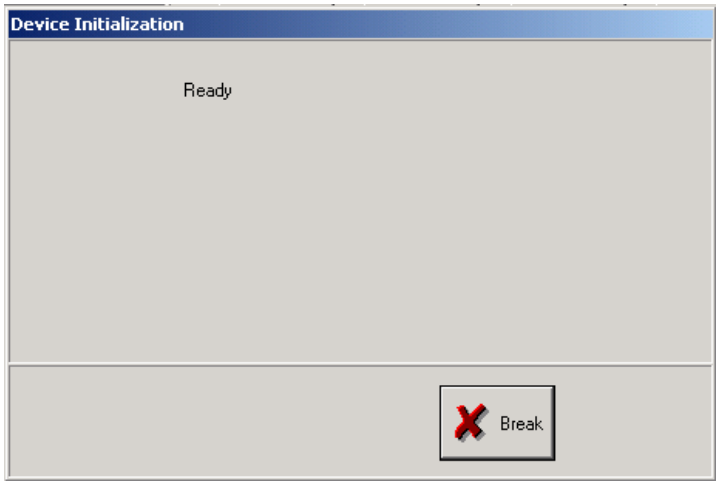
During the initialization procedure, the following pop-up will appear first:



The entire procedure will finish when the last pop-up appears:







When the above pop up disappears from the screen, initialization is completed and instrument is ready to be used.